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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/242,054	02/08/1999	MICHAEL TERENCE BLACK	GM50023	9484
7590	12/28/2010		EXAMINER	
AUTHUR JACKSON			DEVI, SARVAMANGALA J N	
DECHERT PRICE & RHOADS			ART UNIT	PAPER NUMBER
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4000 BELL ATLANTIC TOWER				
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			12/28/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/242,054	Applicant(s) BLACK ET AL.
	Examiner S. Devi, Ph.D.	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-26 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) ____ is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

Lack of Unity

- 1)** Claims 1-26 are under prosecution.
- 2)** As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (“requirement of unity of invention”). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

- 3)** As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

4) Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-9, 25 and 26, drawn to drawn to an isolated polynucleotide, a vector and a host cell.
- II. Claims 10-12, drawn to a method of using the host cell or vector of invention I.
- III. Claims 13 and 14, drawn to a polypeptide comprising an amino acid sequence at least 70% identical to SEQ ID NO: 2 or 4.
- IV. Claim 15, drawn to an antibody against the polypeptide of invention III.
- V. Claim 16, drawn to an antagonist that inhibits the activity of the polypeptide of invention III.
- VI. Claims 17 and 18, drawn to a method for treatment comprising administering the polypeptide of invention III.
- VII. Claim 19, drawn to a method of treatment comprising administering the antagonist of invention V.

VIII. Claim 20, drawn to a process for diagnosing a disease comprising determining a nucleic acid sequence encoding the polypeptide of invention III.

IX. Claim 21, drawn to a diagnostic process comprising analysing the presence of the polypeptide of invention III.

X. Claim 22 (in part), drawn to a method for identifying compounds that inhibit the activity of the polypeptide of invention III.

XI. Claim 22 (in part), drawn to a method for identifying compounds that activate the activity of the polypeptide of invention III.

XII. Claim 23, drawn to a method of inducing an immunological response comprising inoculating with ratA, a fragment or variant thereof.

XIII. Claim 24, drawn to a method of inducing an immune response comprising delivering nucleic acid vector expressing ratA.

5) Inventions I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The special technical feature of the first claimed invention is an isolated polynucleotide comprising at least 15 sequential bases of SEQ ID NO: 1 or 3, or having at least 70% identity thereto. However, such a polynucleotide was already disclosed in the art at the time of the invention by Kunsch et al. (US 6,420,135).

AR218775
LOCUS AR218775 19702 bp DNA linear PAT 25-SEP-2002
DEFINITION Sequence 7 from patent US 6420135.
ACCESSION AR218775
VERSION AR218775.1 GI:23319709
KEYWORDS
SOURCE Unknown.
ORGANISM Unknown.
Unclassified.
REFERENCE 1 (bases 1 to 19702)
AUTHORS Kunsch,C.A., Choi,G.H., Dillon,P.S., Rosen,C.A., Barash,S.C., Fannon,M.R. and Dougherty,B.A.

TITLE Streptococcus pneumoniae polynucleotides and sequences
JOURNAL Patent: US 6420135-A 7 16-JUL-2002;
Human Genome Sciences, Inc.; Rockville, MD;
WOX;
FEATURES Location/Qualifiers
source 1. .19702
/organism="unknown"
/mol_type="genomic DNA"
ORIGIN
Query Match 96.9%; Score 1419.2; DB 9; Length 19702;
Best Local Similarity 98.1%;
Matches 1436; Conservative 0; Mismatches 28; Indels 0; Gaps 0.
Qy 1 ATGACTTTAACATAAAACTATTGAAGAGTGCACAACTCTTGTCTAAGGAAATT 60
Db 3225 ATGACTTTAACATAAAACTATTGAAGAGTGCACAACTCTTGTCTAAGGAAATT 3284
Qy 61 TCTGCAACAGAAATTGACCCAAGCAACACTTGAAAATATCAAGTCTCGTGAGGAAGCCATC 120
Db 3285 TCTGCAACAGAAATTGACCCAAGCAACACTTGAAAATATCAAGTCTCGTGAGGAAGCCCTC 3344
Qy 121 AATTCAATTGTCACCATCGCTGAGGAGCAAGCTCTGTTCAAGCTAAAGCATTGTGAA 180
Db 3345 AATTCAATTGTCACCATCGCTGAGGAGCAAGCTCTGTTCAAGCTAAAGCATTGTGAA 3404
Qy 181 GCTGGAATTGATGCTGACAATGCTTTCCAGGAATTCCACTTGCTGTTAAGGATAACATC 240
Db 3405 GCTGGAATTGATGCTGACAATGCTTTCCAGGAATTCCACTTGCTGTTAAGGATAACATC 3464
Qy 241 TCTACAGACGGTATTCTCACAACTGCTGCCTCAAAATGCTCTACAATATGAGCCAATC 300
Db 3465 TCTACAGACGGTATTCTCACAACTGCTGCCTCAAAATGCTCTACAATATGAGCCAATC 3524
Qy 301 TTTGATGCGACAGCTGTGCCAATGCAAAAACCAAGGCATGATTGTCGTTGGAAAGACC 360
Db 3525 TTTGATGCGACAGCTGTGCCAATGCAAAAACCAAGGCATGATTGTCGTTGGAAAGACC 3584
Qy 361 AACATGGACCAATTGCTATGGGGTGTCAAGGTGAAACTTCACACTACGGAGCAACTAA 420
Db 3585 AACATGGACCAATTGCTATGGGGTGTCAAGGTGAAACTTCACACTACGGAGCAACTAA 3644
Qy 421 AACGCTTGGGACACAGCAAGGTTCTGGGGTCATCAAGTGGTTCTGCCGAGCTGTA 480
Db 3645 AACGCTTGGGACACAGCAAGGTTCTGGGGTCATCAAGTGGTTCTGCCGAGCTGTA 3704
Qy 481 GCCTCAGGACAAGTTCGCTTGCACTTGGTTCTGATACTGGGGTCCATCCGCCAACCT 540
Db 3705 GCCTCAGGACAAGTTCGCTTGCACTTGGTTCTGATACTGGGGTCCATCCGCCAACCT 3764
Qy 541 GCTGCCCTCAACGGAATCGTTGGTCTCAAAACCAACCTACGGACAGTTCACGTTTCGGT 600
Db 3765 GCTGCCCTCAACGGAATCGTTGGTCTCAAAACCAACCTACGGACAGTTCACGTTTCGGT 3824
Qy 601 CTCATTGCCCTTGGTAGCTCATTAGACCAGATTGGACCTTTGCTCTACTGTTAAGGAA 660
Db 3825 CTCATTGCCCTTGGTAGCTCATTAGACCAGATTGGACCTTTGCTCTACTGTTAAGGAA 3884
Qy 661 AATGCCCTCTGCTCAACGCTATTGGCAGCGAAGATGCTAAAGACTCTACTCTGCTCC 720

Db 3885 AATGCCCTCTGCTCAACGCTATTGCCAGCGAAGATGCTAAAGACTCTACTCTGCTCCT 3944
Qy 721 GTCCGCATCGCCGACTTTACTTCAAAATCGGCCAAGACATCAAGGGTATGAAAATCGCT 780
Db 3945 GTCCGCATCGCCGACTTTACTTCAAAATCGGCCAAGACATCAAGGGTATGAAAATCGCT 4004
Qy 781 TTGCTAAGGAATACTCCGGTAAGGAATTAAACCCAGAGGTTAAGGAAACCATTCTAAAT 840
Db 4005 TTGCTAAGGAATACTCCAGGCCAGGAATTGATCAGAGGTTAAGGAAACAATCTTAAAC 4064
Qy 841 GCGCCTAACACCTTGGAAATTGGGTGATTGCGAAGAAGTCAGCCTTCCTCACTCT 900
Db 4065 CGCGCCAACACCTTGGAAATTGGGTGATTGCGAAGAAGTCAGCCTTCCTCACTCT 4124
Qy 901 AAATACCGGAGTTCGCCGTACTACATCATCGCTTCATCAGAAGCTTCATCAAATTGCAA 960
Db 4125 AAATACCGGAGTTCGCCTTTATTACATCATCGCTTCATCAGAAGCTTCATCAAATTGCAA 4184
Qy 961 CGCTTCGACGGTATCCGTTACCGGTATCGCGCAGAAGATGCAACCAACCTTGATGAAATC 1020
Db 4185 CGCTTCGACGGTATCCGTTACCGGTATCGCGCAGAAGATGCAACCAACCTTGATGAAATC 4244
Qy 1021 TATGTAACAGCGGAAGCCAAGGTTTGGTAAGAAGTGAAGCGCCGTATCATGCTGGGT 1080
Db 4245 TATGTAACAGCGGAAGCCAAGGTTTGGTAAGAAGGTTAACGTCGTATCATGCTGGGT 4304
Qy 1081 ACTTTCAGTCTTCATCAGGTTACTACGATGCCACTATAAGAAGGCTGGACAGGTCCTG 1140
Db 4305 ACTTTCAGTCTTCATCAGGTTACTATGATGCCACTACAAAAGGCTGGTCAAGTCCTG 4364
Qy 1141 ACACATTATCATTCAAGATTGCAAAAGTCTCGCGGATTACGATTGATTTGGGTC 1200
Db 4365 ACCCTCATCATTCAAGATTGCAAAAGTCTCGCGGATTACGATTGATTTGGGTC 4424
Qy 1201 ACTGCTCCAAGTGTGCTATGACTTGGATTCTCAACCATGACCCAGTTGCCATGTAC 1260
Db 4425 ACTGCTCCAAGTGTGCTATGACTTGGATTCTCAACCATGACCCAGTTGCCATGTAC 4484
Qy 1261 TTAGCGCACCTATTGACCATACCTGTAACCTGGCAGGACTGCCCTGGATTTGATTCC 1320
Db 4485 TTAGCGCACCTATTGACCATACCTGTAACCTGGCAGGACTGCCCTGGATTTGATTCC 4544
Qy 1321 GCTGGATTCTCTCAAGGTCACCTGTCGGACTCCAATTGATTGGTCCAAGTACTTGAG 1380
Db 4545 GCTGGATTCTCTCAAGGTCACCTGTCGGACTCCAATTGATTGGTCCAAGTACTTGAG 4604
Qy 1381 GAAACCATTACCAAGCTGCTCTGCTTTGAGCACACACAGACTACCAACAAACACAA 1440
Db 4605 GAAACCATTACCAAGCTGCTGCTGCTTGTGAGCACACACAGACTACCAACAAACACAA 4664
Qy 1441 CCCGTGATTGGAGGTGACAAC 1464
Db 4665 CCCGTGATTGGAGGTGACAAC 4688

Thus, the special technical of the first claimed invention is taught by the prior art, and therefore does not define over the prior art. Although the first claimed product of invention I, the method of making the product, and the method of using the

product, is a permitted combination under PCT Rule 13.2, in the instant case, since the product is already disclosed in the art, the special technical feature is not a unifying feature. Technically, the absence of special technical feature permits the separation of the method of using or making the product from the product itself. The special technical features of the subsequently claimed inventions are delineated above. The polypeptide of invention III, the antibody of invention IV, and the antagonist of invention V, do not share significant common structure with the polynucleotide of invention I. A polypeptide is a single chain molecule which comprises amino acid residues. A nucleic acid molecule comprises purine and pyrimidine units. An antibody is a glycoprotein which includes IgG that comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. An antagonist is a chemical compound. Furthermore, the polynucleotide of invention I, the polypeptide of invention III, the antibody of invention IV and the antagonist of invention V, are divergent with regard to their composition, structure, function, and class or subclass, each requiring separate and non-coextensive searches. Furthermore, the methods of inventions II and VI-XIII do not share significant common method steps and parameters, products or reagents used, method objectives and/or the ultimate goals accomplished.

6) With regard to invention III and inventions VI-VIII, the Office has separated product and process claims based on restriction. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of

MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

7) In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper lack of unity between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See ‘Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)’, 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8) Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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9) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

10) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

11) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's acting Supervisor, Patricia Duffy, can be reached on (571) 272-0855.

/S. Devi/
Primary Examiner
AU 1645

December, 2010